IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICAL MUTUAL OF OHIO, INC, on behalf of itself and all others similarly situated,	**CLASS ACTION COMPLAINT**
Plaintiff,	**Civil Action No.**
v.	**JURY TRIAL DEMANDED**
BRAINTREE LABORATORIES, INC.,	
Defendant.	

CLASS ACTION COMPLAINT

Plaintiff Medical Mutual of Ohio, Inc. ("MMOH" or "Plaintiff") brings this antitrust action, on behalf of itself and the class defined below, against Defendant Braintree Laboratories, Inc. ("Braintree" or "Defendant") and alleges as follows based upon personal knowledge as to matters relating to itself and upon the investigation of its counsel and information and belief as to all other matters:

NATURE OF THE CASE

1. This case arises from Braintree's anticompetitive scheme to block entry of generic competition in order to maintain its monopoly power in the United States over MiraLAX (polyethylene glycol 3350) and any actual or potential A-rated generic competitors. Braintree's scheme was intended to, and succeeded in, allowing it to charge supracompetitive prices for polyethylene glycol 3350 (a/k/a PEG), causing Plaintiff and the Class (defined below) to pay overcharges on its purchases of brand or generic PEG (*i.e.*, brand or generic versions of MiraLAX).

2. Braintree sells polyethylene glycol 3350 in the United States under the brand name MiraLAX. MiraLAX is an osmotic laxative that causes water to be retained in the stool. MiraLAX was approved by the United States Food & Drug Administration ("FDA") in February 1999 for the treatment of occasional constipation.

3. As alleged in greater detail herein, Braintree engaged in a scheme involving U.S. Patent No. 5,710,183 (the "'183 patent") issued by the United States Patent and Trademark Office ("PTO"). This misconduct involved, *inter alia*, the improper listing of the '183 patent with the FDA, and improperly asserting infringement claims based on the '183 patent.

4. Braintree proceeded improperly to procure the listing of the '183 patent with the FDA, in order to position itself to enforce the patent by filing patent infringement claims against any potential competitor seeking FDA approval to manufacture and sell a competing, generic version of MiraLAX. Braintree knew that the mere filing of such patent infringement claims would block the market entry of potential competitors, irrespective of the merits of the claims.

5. Braintree then instituted a baseless lawsuit against a potential competitor for the purpose of forestalling generic competition. In May 2003, Braintree filed a patent infringement lawsuit against Schwarz Pharma Manufacturing, Inc. ("SPMI"), a company seeking FDA approval to market a generic version of MiraLAX, even though Braintree knew that the '183 patent was improperly procured and that no reasonable claim of infringement could be based upon it.

6. Braintree had no reasonable argument that SPMI's generic product – labeled for the treatment of constipation – would induce infringement of the '183 patent, which was directed to improve bowel motility and/or stool formation. To the extent that SPMI's generic product could induce infringement because bowel motility and/or stool formation are synonymous with

constipation, then two prior art references anticipate and invalidate the '183 patent. Braintree was faced with a "Catch-22," as, under either analysis, Braintree had no objectively or subjectively reasonable basis to bring its patent infringement suit against SPMI. Nonetheless, Braintree filed suit against SPMI, delaying generic entry of MiraLAX.

7. Braintree filed its infringement lawsuit not for any legitimate purpose, but because it knew that the mere filing of such litigation would raise barriers to the entry of generic competition, including automatically delaying the FDA's granting of final marketing approval to SPMI's generic version of MiraLAX. Without such approval, generic manufacturers cannot bring their products to market.

8. By its unlawful acts, Braintree willfully and unlawfully maintained its monopoly power over MiraLAX and generic and bioequivalent forms of the drug.

9. Braintree's anticompetitive scheme was successful for a time in protecting its revenues from MiraLAX from generic competition.

10. As a direct and proximate result of Defendant's unlawful conduct, MMOH, a third-party payor for MiraLAX, has been denied the benefits of free and unrestrained competition in the polyethylene glycol 3350 market.

11. Specifically, MMOH (and other indirect purchasers who comprise the class defined below) has been denied the opportunity to choose between the MiraLAX brand-name prescription products and generic versions of these medications which would have been priced well below MiraLAX.

PARTIES

12. Plaintiff Medical Mutual of Ohio, Inc. is a non-profit corporation organized under the laws of Ohio. It maintains its headquarters at 2060 E. Ninth Street, Cleveland, Ohio 44115. MMOH paid for Miralax in the following states Alabama, Arkansas, Arizona, California,

Colorado, Connecticut, Florida, Georgia, Iowa, Illinois, Indiana, Kansas, Kentucky, Maryland, Michigan, Missouri, Mississippi, North Carolina, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, West Virginia and the District of Columbia.

13. Defendant Braintree Laboratories, Inc. is a privately held corporation organized and existing under the laws of the Commonwealth of Massachusetts, having its principal place of business at 60 Columbian Street West, Braintree, Massachusetts 02185-0929.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332 as amended by the Class Action Fairness Act of 2005 because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which some members of the Class are citizens of states different than Defendants. See 28 U.S.C.§ 1332(d)(2)(A).

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) because Defendant resides, transacts business, is found, and/or has agents in this district, and because a substantial portion of the affected trade and commerce described below has been carried out in this district.

CLASS ALLEGATIONS

16. Plaintiff brings this action under Rule 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and the following class (the "Class"):

> All persons and entities in the United States and U.S. territories, who from December 23, 2003, until the effects of Defendant's anticompetitive conduct cease (the "Class Period"), indirectly purchased, paid for and/or reimbursed for MiraLax and/or any generic version thereof for consumption by their members, employees, insureds, participants or beneficiaries, and as to whom law or equity affords a claim upon which relief can be granted. Excluded from the Class are Defendant and its parents, employees, subsidiaries, and affiliates.

17. The Class is so numerous that joinder of all members is impracticable. Plaintiff believes that the Class numbers one hundred or more.

18. There are questions of law or fact common to the Class, including:

a. whether Braintree willfully obtained and/or maintained monopoly power over polyethylene glycol 3350 and its actual or potential generic equivalents;

b. whether the '183 patent was issued erroneously;

c. whether Braintree's lawsuit asserting infringement of the '183 patent was baseless;

d. whether Braintree filed such lawsuit for the purpose of preventing or delaying competition;

e. whether, and to what extent, Braintree's conduct caused indirect purchasers of MiraLax to be overcharged and therefore injured; and

f. whether Braintree acted in a matter generally applicable to the Class.

19. These and other questions of law and fact are common to the members of Class and predominate over any questions affecting only individual members.

20. Plaintiff's claims are typical of the claims of the Class because all Class members suffered antitrust injury in the same way as a result of Defendant's wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

21. Plaintiff will fairly and adequately represent and protect the interest of the Class. Plaintiff has retained counsel experienced in class action and pharmaceutical antitrust litigation,

and Plaintiff has no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

22. A class action is superior to any other available methods for the fair and efficient adjudication of this controversy. Plaintiff knows of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

BACKGROUND

Federal Regulation of Prescription Drugs

A. Brand-Name Drugs vs. Generic Drugs

23. Over $250 billion was spent on prescription drugs in the United States in 2005, with $229.5 billion spent on brand-name drugs.

24. Securing the availability of generic drugs is one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which must be approved by the FDA, by law have the same active chemical composition and provide the same therapeutic effects as the brand-name drugs to which they correspond.

25. The FDA will assign an "A" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs. To be deemed a therapeutic equivalent, and assigned an "A" rating by the FDA, the generic drug must contain the same active ingredient(s), dosage form, route of administration, and strength. According to the FDA, a bioequivalent drug rated "A" may be substituted for the reference pioneer or branded drug.

26. Once the safety and effectiveness of a new prescription drug is approved by the FDA, the drug may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be purchased from a licensed pharmacist. The pharmacist, in turn, must fill the prescription with the drug brand

specified by the physician, unless an A-rated generic version of that pioneer drug approved by the FDA is available.

27. If a generic version of a brand-name drug exists and the physician has not specifically indicated to the pharmacist to dispense the branded drug then: (i) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug, and (ii) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the option of purchasing the branded drug or the A-rated generic drug at a lower price.

28. Once a physician writes a prescription for a brand-name drug such as MiraLAX, that prescription defines and limits the market to the drug name or it's A-rated generic equivalents. Only drugs that are A-rated by the FDA may be substituted by a pharmacist for a physician's prescription for the brand-name drug.

29. Generic drugs are priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office ("CBO") concluded that generic drugs save purchasers between $8 billion and $10 billion a year.

30. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug. As additional manufactures bring generic versions of the drug to market, the price continues to drop.

31. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition. The 1998 CBO study estimated that, at that time, generic drugs captured at least 44% of the brand-name drug's market share in just the first year of sale.

B. Federal Scheme for Approval of Pioneer Drugs

32. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301, *et seq*. (The "FD&C Act") regulates the manufacture and distribution of drugs and medical devices in the United States. Under the FD&C Act, approval by the FDA (the governmental body charged with the regulation of the pharmaceutical industry) is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 335(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 335(b) of the FD&C Act, demonstrating that the drug is safe and effective for its intended use.

33. New drugs that are approved for sale in the United States by the FDA are often covered by patents, which provide the patent owner with the ability to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patent, plus any extension of the original patent granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §355 ("Hatch-Waxman Act").

34. Pursuant to 21 U.S.C. § 335(b), in its NDA, the pioneer drug manufacturer must list those patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. Once the NDA is approved by the FDA, any such patents are listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

35. Federal regulations impose strict limitations on the types of the patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits

NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

36. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has regrettably become common for brand-name pharmaceutical companies to list in the Orange Book any and every patent they can obtain, in order to force generic manufactures to file what, as described below, is commonly known as a Paragraph IV Certification.

37. The FDA does not police the listing of patents. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing in the Orange Book. The FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information . . . .").

38. The FDA's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing.

C. Approval of Generic Drugs

39. Congress enacted the Hatch-Waxman Act in 1984. The Hatch-Waxman Act was principally designed to streamline the process by which generic drugs are brought to market. The Hatch-Waxman Act simplified the regulatory hurdles faced by prospective generic drug manufactures by eliminating the need for such manufactures to file lengthy and costly NDAs. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand-name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA"), pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand-name drug.

40. Under the Hatch-Waxman Act, a generic drug manufacturer's ANDA must contain one of four certifications pursuant to 21U.S.C. § 355(j)(2)(A)(vii) addressing the patents, if any, listed in the Orange Book as applying to the brand-name or pioneer drug. Four types of certifications are available:

I. The brand name manufacture has not filed patent information with the FDA (a "Paragraph I Certification");

II. The patent or patents listed in the Orange Book have expired (a "Paragraph II Certification");

III. The patent or patents listed in the Orange Book will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III Certification"); or

IV. The patent or patents listed in the Orange Book are invalid or not infringed by the generic manufacturer's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii).

41. If a generic manufacturer files a Paragraph IV Certification, seeking to market the generic drug before patent expiration and asserting that any listed patent is invalid or will not be infringed, the brand-name manufacturer has the opportunity to delay the generic manufacturer's receipt of final FDA approval, and, thus, its ability to come to market. This is because a generic manufacturer filing a Paragraph IV Certification must promptly give notice of this fact to both the NDA owner and the owner of the patent(s) at issue, and this certification constitutes a "technical act of infringement" under the Hatch-Waxman Act.

42. The filing of a Paragraph IV Certification thus creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

43. Because of this thirty-month stay of ANDA approval, the mere filing of an infringement action in response to a Paragraph IV Certification, regardless of the action's underlying merit, gives the brand-name company the equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without requiring the brand company to establish likelihood of success on the merits, irreparable harm, that the balance of hardships tips in its favor, or that the public good is served by the blocking of entry.

44. As a practical matter the brand name company wins the lawsuit simply by filing it, as it automatically protects its monopoly for up to two-and-a-half years while the infringement action winds its way through the court system. Moreover, the brand name company has an incentive to stall the progress of the litigation. There are no disgorgement provisions for profits earned during the thirty-month period of exclusivity if a court eventually determines that the suit was without merit.

45. An improper Orange Book listing also has additional anticompetitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufactures. 21 U.S.C. § 355(j)(5)(B)(iv). Absent an improper Orange Book listing, no Paragraph IV Certification would be required and, thus, no generic company would receive any 180-day exclusivity; rather, multiple generic competitors would enter the market simultaneously,

resulting in prices even lower than one would find during the 180-day exclusivity period when only one generic manufacturer is permitted to market its product.

46. Defendant was at all times fully familiar with the ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Amendments.

BRAINTREE'S ANTICOMPETITIVE CONDUCT

47. Braintree successfully forestalled generic competition to MiraLAX from entering the market, thereby depriving purchasers of the benefits of cheaper polyethylene glycol 3350 products, by improperly listing the '183 patent in the Orange Book, and by bringing a patent infringement lawsuit based on the '183 patent.

A. The '183 Patent Approval, Acquisition by Braintree, and Listing in the Orange Book

48. Braintree has asserted that the '183 patent covers MiraLAX and bars generic competition. The '183 patent claims, *inter alia*, a composition for the improvement of bowel function comprising polyethylene glycol and a fiber bulking agent, wherein the polyethylene glycol is present in a weight ratio of polyethylene glycol to fiber of at least about 1:2 and no more than about 7:1.

49. The patent application was filed on July 14, 1995. George M. Halow of El Paso, Texas was listed as the inventor.

50. During the prosecution of the '183 patent, the Examiner issued an Office Action dated February 25, 1997, rejecting claims 1-33 in the '183 patent. The Examiner found that the combination of several references–Kais, Powell, Parker/Kimura, and Fordtran–teach polyethylene glycol with a fiber bulking agent.

51. Original claim 34, which ultimately issued as claim 33, claims "a method for improving bowel function in a mammal, comprising orally administering polyethylene glycol to the mammal in an amount sufficient to improve bowel motility, stool formation or both." Claim 34 (issued as claim 33) makes no reference to use of a fiber bulking agent.

52. The Examiner separately rejected claim 34 as obvious in light of Kimura or Fordtran, as both references teach compositions containing polyethylene glycol to improve bowel movement.

53. Halow, and/or individuals acting on his behalf, represented to the PTO in a response dated May 27, 1997, that claims 1-34 "provide a unique composition containing polyethylene glycol and a fiber bulking agent wherein PEG is present in a weight ratio of polyethylene glycol to fiber of from about 1 to 2 to no more than about 7 to 1. These percentages are critical and nowhere are they discussed or taught in the base references or the alleged equivalence teaching set forth by the secondary references."

54. Additionally, Halow and/or individuals acting on his behalf emphasized in the response the critical nature of the ratio of polyethylene glycol and fiber by explaining that if "the PEG to fiber ratio is too low, rapid onset of activity of the products of the invention drops off and begins to approach the low onset of a fiber based bulk laxative of the prior art. If the PEG to fiber ratio is too high, the volume of composition which must be ingested to obtain the benefits of the fiber content may be too high and the excess PEG may result in undesirable effects, such as those associated with PEG based bowel lavage compositions, such as those set forth in Kimura, *et al* or Fordtran."

55. The Examiner issued a Notice of Allowance reasoning that "the claims are considered to distinguish over the prior art since there is no teaching of the ratio for the two active ingredients."

56. The '183 patent was issued on January 20, 1998.

57. Crucially, 32 of the 33 claims in the '183 patent were limited by the ratio for the two active ingredients (*i.e.*, polyethylene glycol and fiber). Claim 33, however, issued unchanged and without this restriction, despite having been rejected by the PTO because it claimed the prior art.

58. On information and belief, Braintree had previously, in approximately 1985 and 1990, sought to patent the use of polyethylene glycol for the treatment of constipation, but each time the PTO rejected Braintree's patent application because the claims were anticipated and/or rendered obvious by the prior art.

59. On information and belief, when Braintree filed its NDA for MiraLAX, Braintree owned no patents that covered MiraLAX or the use of MiraLAX.

60. On information and belief, Braintree learned, much to its shock, about the '183 patent while Braintree's NDA for MiraLAX was pending.

61. On information and belief, Braintree's counsel examined the '183 patent issued to Halow and concluded, in a December 23, 1998 letter sent to Halow, that claim 33 of the '183 patent was directly anticipated by the prior art, and hence invalid.

62. On information and belief, Braintree paid Halow a nuisance-value payment of approximately $15,000 for a non-exclusive license of the '183 patent.

63. On information and belief, Braintree nevertheless listed the '183 patent in the FDA's Orange Book in 1999, the same year that Braintree received final marketing approval for its MiraLAX NDA and began selling MiraLAX.

64. On information and belief, Braintree did not purchase the '183 patent outright from Halow until late 2001, shortly before MiraLAX would lose its marketing exclusivity on February 18, 2002.

B. Braintree's Filing of a Sham Lawsuit

65. On January 30, 2003, SPMI submitted an ANDA with the FDA for a generic version of Braintree's MiraLAX. SPMI called its generic product GlycoLax. SPMI's GlycoLax is comprised of only polyethylene glycol and does not contain a fiber bulking agent as explicitly required by claims 1–32 of the '183 patent.

66. In accordance with 21 U.S.C. § 355(j)(5)(B), SPMI sent Braintree a Paragraph IV certification letter on April 1, 2003.

67. On May 16, 2003, Braintree filed suit under 35 U.S.C. § 271(e)(2)(A) against SPMI for infringement of the '183 patent in the United States Court for the District of Delaware, thereby invoking the Hatch-Waxman Act's automatic 30-month stay. Braintree did not assert claims 1–32. Instead, Braintree sued for patent infringement only as to method claim 33, which recites "a method for improving bowel function in a mammal, comprising orally administering polyethylene glycol to the mammal in an amount sufficient to improve bowel motility, stool formation or both."

68. On September 3, 2003, more than three months after it filed the action, Braintree finally served a complaint on SPMI.

69. Braintree knew or should have known that its claim against SPMI was baseless because, *inter alia*, any interpretation of claim 33 that would support infringement by SPMI

would necessarily render claim 33 invalid. Furthermore, the legal grounds for Braintree's induced infringement claim were objectively baseless and a sham because such grounds were directly contravened by the ruling in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), that was issued four months *before* Braintree filed its infringement action.

70. Because claim 33 is a method claim, it is directly infringed (if at all) only by patients that perform the claimed method. SPMI could infringe (if at all) only indirectly by inducing patients to infringe. To prevail in its action under 35 U.S.C. § 271(e)(2)(A), Braintree was required not only (1) to prove that patients would directly infringe claim 33 under a construction that could sustain that claim's validity, but also (2) to prove that SPMI's conduct constituted inducement of infringement under that same claim construction. Braintree's lawsuit against SPMI was objectively baseless because Braintree could not reasonably expect to prevail on either issue, much less both issues as required. Furthermore, Braintree's lawsuit was objectively baseless on its face because, to prevail, Braintree was required to advance a claim construction position for purposes of validity that precluded any reasonable argument of inducement by SPMI, and vice versa.

71. Braintree's infringement theory was objectively baseless because Braintree could not reasonably expect to prevail in proving direct infringement of claim 33 by patients under a claim construction that would support validity. Specifically, Braintree knew or should have known: (a) that the Examiner's objections to the claims issued in the '183 patent were only overcome by representations from Halow and/or persons acting on his behalf that it was the ratio of polyethylene glycol to the fiber bulking agent that was "critical" to the patent application and such ratio was not taught or otherwise rendered obvious by the prior art; (b) that the claims of the '183 patent, if read to cover the administration of pure polyethylene glycol compositions, would

be inconsistent with the PTO examiner's basis for allowing the claims in the first instance; (c) that if claim 33 were construed to cover the administration of polyethylene glycol alone for the treatment of constipation, claim 33 is invalid in view of prior art; (d) that if claim 33 were construed to cover the administration of polyethylene glycol alone for the treatment of constipation, there were invalidating public uses of the patented subject matter outside the one year grace period set forth in 35 U.S.C. § 102(b); (e) that, even assuming that claim 33 could cover the administration of polyethylene glycol alone for the treatment of constipation, there was no disclosure of polyethylene glycol only compositions in the specification of the '183 Patent, or their preparation or application, in accordance with the requirements of 35 U.S.C. § 112; and (f) that the use of compositions comprising polyethylene glycol to treat constipation was known for twenty years prior to the filing of the Halow application on July 14, 1995. Alternatively, Braintree knew or should have known that claim 33 cannot be construed to cover the use of polyethylene glycol alone and that SPMI's GlycoLax is comprised of only polyethylene glycol. GlycoLax does not contain a fiber bulking agent.

72. Braintree's infringement theory was also objectively baseless because, even assuming that Braintree could reasonably expect to prevail in proving direct infringement of claim 33 by patients, Braintree could not reasonably expect to prevail in proving inducement *by SPMI*, the only entity that Braintree sued. To overcome SPMI's invalidity theories, Braintree was forced to argue that claim 33 required improving bowel motility or stool formation rather than merely treating constipation. However, nothing in SPMI's labeling or ANDA encourages the use of PEG for the improvement of bowel motility or stool formation. Instead, SPMI's labeling promoted PEG for precisely what was admittedly disclosed in the prior art – namely the

treatment of constipation. Accordingly, it was unreasonable to argue that SPMI was encouraging patients to take GlycoLax to improve bowel motility or stool formation.

73. In an attempt to overcome SPMI's invalidity defense, Braintree was forced to distinguish "the treatment of constipation by softening the stool" from "using PEG to improve bowel motility and/or stool formation." DE 256 ¶ 891. Indeed, Braintree specifically distinguished constipation on the one hand from both bowel motility and stool formation on the other by stating that "[m]ost patients with constipation do not have a bowel motility or stool formation problem." DE 251 ¶ 226. Braintree argued that "[p]atients with normal transit constipation may still have dismotility of the bowel, meaning alterations in the neuromuscular contractions of the bowel, but would not necessarily have bowel motility problems." DE 251 ¶ 227. Braintree also argued that "giving PEG to soften stool would not necessarily improve stool formation. For example, softening the stool of a person having a stool form of five would make that person's stool formation worse." DE 251 ¶ 267. If the treatment of constipation does not necessarily require improving bowel motility or stool formation, then SPMI could not reasonably be viewed as encouraging patients to utilize GlycoLax to improve bowel motility or stool formation simply by encouraging patients to utilize GlycoLax for constipation.

74. Braintree's infringement theory was premised on an absurdity – namely, that although the use of PEG for the treatment of constipation was admittedly prior art to the '183 Patent, Braintree was nevertheless entitled to exclude SPMI from marketing PEG for the treatment of constipation and to exclude the public from utilizing PEG for the treatment of constipation. *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1346 (Fed Cir. 1999) ("[I]f granting patent protection on the disputed claim would allow the patentee to exclude the public

from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art.").

75. Braintree's lawsuit against SPMI was also subjectively baseless. This Court found following trial that "[a]s an initial matter, the court agrees that the chronology of events supports the inference that Braintree's infringement suit was motivated primarily by business considerations, rather than legal ones." It also found that "Braintree obtained and relied upon an admittedly 'weak' patent for protection from other generic competition." Braintree's own counsel concluded before filing the lawsuit that "[a]fter evaluating the file history of this patent, we have concluded that, if this patent were to be reexamined by the USPTO, claim 33 (PEG alone) would be found invalid in view of the prior art . . . . It is our opinion that claim 33 . . . is directly anticipated by the claims of Fordtran." Braintree knew that (1) it had tried for years to get a patent on the use of PEG alone for the approved use of treating constipation; (2) it abandoned those efforts when the claims were found to be unpatentable based on prior art; and (3) it was shocked to find the Halow patent.

76. On December 23, 2003, SPMI received a tentative approval letter from the FDA for its ANDA for GlycoLax. This approval would have become final but for Braintree's baseless lawsuit claiming that SPMI infringed claim 33 of the '183 patent. Indeed, as discussed below, Braintree's baseless lawsuit delayed even tentative approval. Absent such conduct, SPMI's generic version of MiraLAX would have been approved and on the market much earlier.

77. On May 21, 2004, Braintree wrote to SPMI that it had decided to voluntarily dismiss its patent infringement claim against SPMI with prejudice and without costs. Braintree also offered SPMI a royalty-free license to claim 33 of the '183 patent.

78. On May 24, 2004, Braintree filed "Plaintiff's Motion for Voluntary Dismissal of Its Complaint and Motion to Dismiss Defendant's First Counter Claim as Moot."

79. On June 3, 2004, the Court dismissed Braintree's complaint with prejudice, ending the remaining portion of the thirty month stay of SPMI's ANDA approval.

80. Less than one month later, on July 2, 2004 the FDA gave final approval of SPMI's ANDA for its GlycoLax product. Within days of the FDA's final approval, GlycoLax was shipped to customers in the United States.

EFFECTS ON COMPETITION

81. Braintree's exclusionary conduct delayed generic competition to MiraLAX and enabled Braintree to sell MiraLAX without generic competition. But for Braintree's misconduct, one or more competitors would have begun marketing A-rated generic versions of MiraLAX much sooner than such versions actually were marketed, and Braintree itself would have entered the market with its own generic version of MiraLAX.

82. Braintree's unlawful conduct caused the ANDA approval process to be delayed by the FDA and caused SPMI to divert its resources from its ANDA application and to expend substantial resources on litigation. Absent the patent lawsuit, SPMI and the FDA would have had reason to, and would have, focused and directed their limited resources into the ANDA approval process for generic polyethylene glycol 3350. Such focus and resources would have brought earlier FDA approval and marketing of generic polyethylene glycol 3350. However, Braintree's baseless suit – because it triggered the Hatch-Waxman Act's automatic 30-month stay that would block marketing regardless of approval – destroyed both SPMI's the FDA's incentives to expedite review and approval of SPMI's ANDA.

83. The FDA expeditiously approves ANDAs when the generic product that is the subject of the ANDA is not the subject of a patent infringement lawsuit under the Hatch-

Waxman Act. For example, when an ANDA filer makes a Paragraph III Certification, certifying that it will only market the drug at issue upon expiration of a patent listed as applying to the drug in the Orange Book, FDA approval typically occurs on the very same day the patent expires.

84. In essentially every instance since the year 2000 involving a brand-name drug coming off patent for which an ANDA filer certified that it would market a generic version of the brand-name drug only upon expiration of the relevant patent (*i.e.* a Paragraph III Certification), the FDA approved the generic applicant the very day (and in a few instances, within one or two days) of the expiration date of the patent. The ANDAs were consistently timely filed and approved regardless of the magnitude of the brand-name drug's annual sales. Moreover, the FDA approved SPMI's ANDA for generic polyethylene glycol 3350 less than one month after Braintree voluntarily dismissed its patent infringement claim against SPMI. Accordingly, absent Braintree's exclusionary conduct here, the FDA would have promptly and timely approved SPMI's ANDA, permitting generic polyethylene glycol 3350 to enter the market substantially before the actual final approval July 2004, and even before the tentative approval in December 2003.

85. Braintree's scheme to delay the introduction into the U.S. marketplace of any generic version of MiraLAX caused Plaintiff and the Class to pay more than they otherwise would have paid for polyethylene glycol 3350.

86. As noted, generic versions of a brand-name drug are initially priced significantly below the brand-name drug. As a result, upon generic entry, purchasers rapidly substitute generic versions of the drug for some or all of their brand purchases. As more generic manufacturers enter the market, prices for generic versions of a drug decrease further because of competition among the generic manufactures. This price competition enables purchasers of the

drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name drug manufactures have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial overcharges from that delay.

ANTITRUST IMPACT UPON PLAINTIFF AND MEMBERS OF THE CLASS

87. During the Class Period, Plaintiff and members of the Class paid for substantial amounts of MiraLAX. As a result of Defendant's illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, artificially inflated prices for its polyethylene glycol 3350 purchases. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendant, Plaintiff and members of the Class would have paid less for polyethylene glycol 3350 by (a) substituting purchases of less-expensive, generic polyethylene glycol 3350 for their purchases of more-expensive branded MiraLAX, (b) receiving discounts and/or lowering prices on their remaining branded MiraLAX purchases, and (c) purchasing generic polyethylene glycol 3350 at lower prices sooner.

88. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

MONOPOLY POWER

89. Prior to the entry of A-rated generic competition, Braintree had monopoly power with respect to its MiraLAX brand. Braintree had the power to maintain the price of MiraLAX at supracompetitive levels profitably, without losing substantial sales.

90. Prior to generic entry, a small but significant, non-transitory price increase by Braintree to MiraLAX would not have caused a significant loss of sales to other products.

91. Prior to generic entry, Braintree sold MiraLAX at prices well in excess of marginal costs and enjoyed high profit margins.

92. Prior to generic entry, Braintree exercised the power to exclude competition.

93. To the extent that defining a relevant product market is necessary in this case, the relevant product market is polyethylene glycol 3350 in brand or generic forms.

94. The relevant geographic market is the United States.

95. During and prior to the Class Period, Defendant held a 100% share in the relevant product market in the United States.

COUNT I:
VIOLATIONS OF STATE ANTITRUST LAWS

96. Plaintiff incorporates by reference the preceding allegations.

97. As described above, Defendant knowingly and willfully engaged in a course of conduct designed to extend its monopoly power. This course of conduct included, *inter alia,* improperly filing a patent infringement action against a generic manufacturer seeking to obtain approval to sell generic versions of MiraLAX.

98. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of the Code of Alabama § 6-5-60, *et seq.,* with respect to purchases of MiraLAX in Alabama by Plaintiff and members of the Class.

99. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of Arizona Revised Stat. §§ 44-1401, *et seq.,* with respect to purchases of MiraLAX in Arizona by Plaintiff and members of the Class.

100. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of Cal. Bus. & Prof. Code §§ 16700, *et seq.,* and Cal. Bus. & Prof. Code §§ 1720, *et seq.,* with respect to purchases of MiraLAX in California by Plaintiff and members of the Class.

101. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of D.C. Code Ann. §§ 28-45031, *et seq.,* with respect to purchases of MiraLAX in the District of Columbia by Plaintiff and members of the Class.

102. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of Iowa law with respect to purchases of MiraLAX in Iowa by Plaintiff and members of the Class.

103. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of Kan. Stat. Ann. §§ 509-101, *et seq.,* with respect to purchases of MiraLAX in Kansas by Plaintiff and members of the Class.

104. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of Mich. Stat. §§ 445.771, *et seq.,* with respect to purchases of MiraLAX in Michigan by Plaintiff and members of the Class.

105. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of Miss. Code Ann. §§ 75-21-1, *et seq.,* with respect to purchases of MiraLAX in Mississippi by Plaintiff and members of the Class.

106. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of Nev. Rev. Stat. Ann. § 598A., *et seq.,* with respect to purchases of MiraLAX in Nevada by Plaintiff and members of the Class.

107. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of New York General Business Law § 340, *et seq.,* with respect to purchases of MiraLAX in New York by Plaintiff and members of the Class.

108. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of N.C. Gen. Stat. §§ 75-1, *et seq.,* with respect to purchases of MiraLAX in North Carolina by Plaintiff and members of the Class.

109. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.,* with respect to purchases of MiraLAX in Tennessee by Plaintiff and members of the Class.

110. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of W. Va. Code §§ 47-18-1, *et seq.,* with respect to purchases of MiraLAX in West Virginia by Plaintiff and members of the Class.

111. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant markets in violation of Wis. Stat. § 133.01, *et seq.,* with respect to purchases of MiraLAX in Wisconsin by Plaintiff and members of the Class.

112. MMOH and members of the Class have been injured in their business or property by reason of Defendant's antitrust violations alleged in this Count. The injury consists of paying higher prices for MiraLAX prescription drugs than MMOH and members of the Class would have paid in the absence of those violations. This injury is of the type the antitrust and consumer protection laws of the above States and the District of Columbia were designed to prevent and flows from that which makes Defendant's conduct unlawful.

COUNT II: VIOLATIONS OF STATE CONSUMER FRAUD AND UNJUST ENRICHMENT LAWS

113. Plaintiff incorporates by reference the preceding allegations.

114. Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when it filed a baseless patent infringement action against SPMI in order to prevent the FDA

from granting final approval of pending applications of would-be competitors to market generic polyethylene glycol 3350. As a direct and proximate result of Defendant's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and members of the Class were deprived of the opportunity to purchase a generic version of MiraLAX, and forced to pay higher prices for polyethylene glycol 3350 during the Class Period.

115. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz Rev. Stat. § 44-1522, *et. seq.*

116. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et. seq.*

117. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et. seq.*

118. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et. seq.*

119. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110B, *et. seq.*

120. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et. seq.*

121. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501-201, *et. seq.*

122. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-392, *et. seq.*

123. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et. seq.*

124. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et. seq.*

125. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et. seq.* 143.

126. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et. seq.*

127. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et. seq.*

128. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Missouri Stat. § 407.0 10, *et. seq.*

129. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et. seq.*

130. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et. seq.*

131. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et. seq.*

132. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et. seq.*

133. Defendant has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. § 15 § 751, *et. seq.*

134. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et. seq.*

135. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et. seq.*

136. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et. seq.*

137. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et. seq.*

138. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et. seq.*

139. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, *et. seq.*

140. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et. seq.*

141. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code. § 19.86.010, *et. seq.*

142. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et. seq.*

143. Plaintiff MMOH and members of the Class have been injured in their business and property by reason of Defendant's anticompetitive, unfair or deceptive acts alleged above. The injury consists of paying higher prices for polyethylene glycol 3350 prescription drugs than Plaintiff and members of the Class would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendant's unlawful conduct.

144. Defendant has benefited from the monopoly on its sales of MiraLAX resulting from the unlawful and inequitable acts alleged in this Complaint.

145. Defendant's financial benefits resulting from its unlawful and inequitable conduct are traceable to overpayments for polyethylene glycol 3350 by Plaintiff and members of the Class.

146. Plaintiff MMOH has conferred upon Defendant an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and members of the Class.

147. The economic benefit of overcharges and unlawful monopoly profits derived by Defendant through charging supra-competitive and artificially inflated prices for MiraLAX is a direct and proximate result of Defendant's unlawful practices.

148. The financial benefits derived by Defendant rightfully belong to Plaintiff and members of the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices, inuring to the benefit of Defendant.

149. It would be inequitable for Defendant to be permitted to retain any of the overcharges for MiraLAX derived from Defendant's unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

150. Defendant should be compelled to disgorge for the benefit of Plaintiff and members of the Class all unlawful or inequitable proceeds received by it.

151. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendant.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter an order:

A. determining that this action may be maintained as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages; and declare Plaintiff as the representative of the Class and its counsel as class counsel under Rule 23(g);

B. declaring Defendant's conduct to be in violation of the antitrust, deceptive practices, and consumer fraud statutes of the states listed above;

C. granting Plaintiff and the Class compensatory, multiple, and punitive damages as permitted by law;

D. granting Plaintiff and the Class the cost of prosecuting this action, together with pre- and post-judgment interest, reasonable attorneys' fees, and costs; and

E. granting Plaintiff and the Class other relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury of all issues so triable.

DATED: July 14, 2010

Respectfully submitted,

MURPHY & LANDON

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